

microchannels through openings in the microchannels at least by spontaneous fluid transport, and a detection zone in uninterrupted fluid communication with the acquisition zone along the microchannels, the detection zone including at least one detection element that facilitates detection of a characteristic of the fluid sample within at least one microchannel of the detection zone.

Bl
End

REMARKS

The above listed claim amendments along with the following remarks are believed to be fully responsive to the Office Action set forth above. Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 are pending and currently under consideration. Claim 1 has been amended. The remainder of originally filed claims 1 – 101, that is claims 10-12, 14-38, 42, 47, 48, 51, 52, 55-59, 62-71, 76, 78-80, and 86-101, have been withdrawn from consideration.

In the Abstract

The Abstract was objected to as having too many words. The Abstract has been amended to reduce the number of words and now has a word count below 150. No new matter has been added by these changes.

Claim Rejections – 35 USC § 112

Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action asserted that the language “uninterrupted fluid flow of a fluid sample throughout the article” is not commensurate in scope with the description of the invention. Claim 1 has been amended to remove the phrase “throughout the article.” Therefore, amended claim 1 and all of its dependent claims are now definite and Applicants respectfully request withdrawal of this rejection.

Claims 8, 9, 49 and 50 were rejected only under § 112, second paragraph. The § 112 rejection having been overcome, these claims are now in condition for allowance, which action Applicants respectfully request.

Claim Rejections – 35 USC § 102

Claims 1-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 77 and 81-85 were rejected under 35 U.S.C. 102(b) and (e) as being anticipated by any one of the following: Beaver et al. (U.S. Pat. No. 4,469,601), Hagen et al. (U.S. Pat. No. 4,810,381), or Fitzpatrick et al. (U.S. Pat. No. 5,451,504). The Office Action asserted that these three patents disclose thin layer detection articles having a fluid control layer as a fibrous material through which sample solution freely and uninterruptedly flows. The Office Action also stated that the fibrous nature of these devices includes a plurality of microchannels therein for fluid flow through the devices.

As recited in claim 1, the present invention is a detection article having at least one fluid control film layer having at least one microstructured major surface including a plurality of microchannels therein. Within the specification of the present patent application, the microstructured film layer and microchannels are clearly distinguished from fibrous absorbent materials. In fact, the specification states “[p]referred fluid control films of the invention are in the form of sheets or films having microstructured surfaces including a plurality of open channels having a high aspect ratio (that is, channel length divided by the wetted channel perimeter), rather than a mass of fibers. The channels of fluid control films usable with the invention preferably provide more effective liquid flow than is achieved with webs, foam, or tows formed from fibers. The walls of channels formed in fibers will exhibit relatively random undulations and complex surfaces that interfere with flow of liquid through the channels. In contrast, the channels in the present invention are precisely replicated, with high fidelity, from a predetermined pattern and form a series of individual open capillary channels that extend along a major surface. These microreplicated channels formed in sheets, films, or tubes are preferably uniform and regular along substantially each channel length and more preferably from channel to channel.” (*emphasis added*; Specification, Page 11).

As stated in the Office Action, the three prior art references disclose articles using “fibrous” material for fluid sample flow. None of these three references either disclose or suggest the use of a microstructure fluid control film layer having a plurality of microchannels, as recited in claim 1. Thus, neither Beaver et al., Hagen et al. nor Fitzpatrick et al. anticipate this claim. Claim 1 is, therefore, patentable over these references.

Withdrawal of the rejection and allowance of this claim is respectfully requested by the Applicants.

The remaining rejected claims all depend from claim 1 and, thus, are patentable for at least the same reasons set forth above. Applicants respectfully request withdrawal of the rejection and allowance of these claims.

In the IDS

Applicants acknowledge the Examiner's statement that the copending applications listed on an IDS, filed on 11/24/00, have been considered, but cannot be listed. Another supplemental IDS is being filed concurrently with this Amendment to update the listing with the patents that have issued from the copending applications identified in the previously submitted IDS.

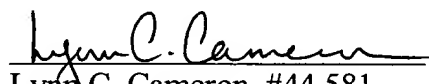
CONCLUSION

All pending claims are now in condition for allowance. A notice to that effect is respectfully requested. Should any issue remain upon entry and consideration of this response, the Examiner is invited to contact Applicants' representative at the number listed below, in order to expedite prosecution of this application.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully Submitted,

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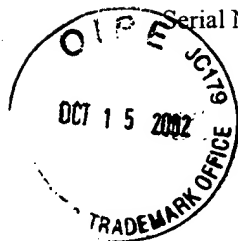
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Dated: October 9, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Amended) A detection article comprising:
at least one fluid control film layer having at least one microstructured major surface including a plurality of microchannels therein, the microchannels configured for uninterrupted fluid flow of a fluid sample ~~throughout the article~~, the film layer including an acquisition zone wherein portions of the plurality of microchannels draw the fluid sample into the plurality of microchannels through openings in the microchannels at least by spontaneous fluid transport, and a detection zone in uninterrupted fluid communication with the acquisition zone along the microchannels, the detection zone including at least one detection element that facilitates detection of a characteristic of the fluid sample within at least one microchannel of the detection zone.



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ABSTRACT OF THE DISCLOSURE

A detection article including at least one fluid control film layer having at least one microstructured major surface with a plurality of

5 microchannels therein. The microchannels configured for uninterrupted fluid flow of a fluid sample. The film layer including an acquisition zone wherein portions of the plurality of microchannels draw the fluid sample into the plurality of microchannels through openings in the microchannels at least by spontaneous fluid transport. The film layer also including a detection zone in uninterrupted

10 fluid communication with the acquisition zone along the microchannels with the detection zone including a detection element that facilitates detection of a characteristic of the fluid sample within a microchannel of the detection zone.

The detection article may be formed from a plurality of film layers that are stacked to form a three-dimensional article. The detection elements may include

15 hardware devices, assay reagents and/or sample purification materials.